



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 18, 2019

Jayne Walz  
Senior Regulatory Manager  
Valent BioSciences LLC  
870 Technology Way  
Libertyville, IL 60048

Subject: Pesticide Registration Improvement Act (PRIA) Labeling and Formulation Amendment – To Add a New Supplier of the Active Ingredient, Add a New Producer of the Product, and Make Other Adjustments to the Basic Confidential Statement of Formula (CSF); Make Adjustments to the Labeling (e.g., Add a Potency Statement); and Make Adjustments to the Basic CSF and Labeling Requested by the EPA (e.g., Update the First Aid and Hazards to Humans and Domestic Animals Statements on the Labeling)  
Product Name: *Bacillus thuringiensis* subsp. *aizawai* Slurry (For XenTari Formulations)  
EPA Registration Number: 73049-63  
Application Date: October 23, 2018  
OPP Decision Number: 545591

Dear Ms. Walz:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

The primary brand name of this product has been changed from *Bacillus thuringiensis* subsp. *aizawai* Slurry to *Bacillus thuringiensis* subsp. *aizawai* Slurry (For XenTari Formulations), and our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 05/22/2019

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this

product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 § CFR 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Susanne Cerrelli by phone at (703) 308-8077 or via email at [cerrelli.susanne@epa.gov](mailto:cerrelli.susanne@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'JKausch', with a stylized flourish at the end.

Jeannine Kausch, Product Manager 92  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure

**BACILLUS THURINGIENSIS SUBSP. AIZAWAI SLURRY (FOR XENTARI FORMULATIONS)**

FOR MANUFACTURING USE ONLY

**ACTIVE INGREDIENT:**

*Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 solids, spores and insecticidal toxins ..... 18.0% w/w\*

**OTHER INGREDIENTS:**..... 82.0% w/w

**Total:** ..... 100.0% w/w

\*Potency: minimum of 4,000 Cabbage Looper Units (CLU) per mg of product (equivalent to 1.8 billion CLU per pound of product)

The % active ingredient does not indicate product performance and potency measurements are not federally standardized.

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

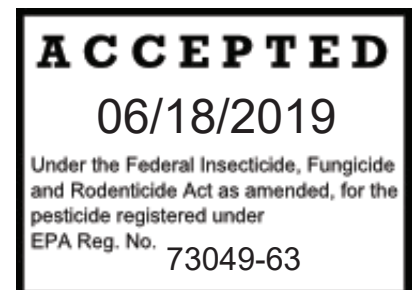
<b>FIRST AID</b>	
<b>If in eyes:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>HOTLINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and or transport emergency information.	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage.	

Not for use or sale after: [Date stamped/placed on labeling will be 6 months after the date of Manufacture]

EPA Registration No. 73049-63  
EPA Establishment No.

Lot No.: \_\_\_\_\_  
Net Contents:

Manufactured [for] [by]: Valent BioSciences LLC  
870 Technology Way  
Libertyville, IL 60048  
1-800-323-9597



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Causes irreversible eye damage. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This slurry is intended for formulation into insecticidal products for use on food and non-food crops.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:**

Store in cool, dry conditions.

**PESTICIDE DISPOSAL:**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER HANDLING:**

**Tanker trucks:** Follow manufacturer's directions for cleaning.